May 22, 2023

GBS Commonwealth Co., Ltd.
Jimmy Kim
C-309, Woolim Lion's Valley, 168, Gasan Digital 1-ro
Geumcheon-gu, Seoul 08507
South Korea

Re: K230708
Trade/Device Name: Peridot-TD Spacer system (The Peridot-TD Intervertebral body fusion system); Anterior cervical interbody fusion-ACIF (The Peridot-TD Anterior Cervical Intervertebral body fusion system)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: March 9, 2023
Received: March 14, 2023

Dear Jimmy Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K230708

Device Name
Anterior cervical interbody fusion - ACIF (The Peridot-TD Anterior Cervical Intervertebral body fusion system), Peridot-TD Spacer system (The Peridot-TD Intervertebral body fusion system)

Indications for Use *(Describe)*
Anterior cervical interbody fusion - ACIF (The Peridot-TD Anterior Cervical Intervertebral body fusion system)

The Peridot-TD Anterior Cervical Intervertebral body fusion system is intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at one or multiple contiguous levels from C2-T1. The Peridot-TD Anterior Cervical Intervertebral body fusion system is also to be used with supplemental fixation systems that have been cleared for use in the cervical spine.
These patients should have had at least six weeks of nonoperative treatment.
The Peridot-TD Anterior Cervical Intervertebral body fusion system is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

Peridot-TD Spacer system (The Peridot-TD Intervertebral body fusion system)

The Peridot-TD Intervertebral body fusion system is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft.
The Peridot-TD Intervertebral body fusion system is to be used with supplemental fixation. Patients should have at least six (6) months of nonoperative treatment prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

# SUMMARY

The following summary is being submitted as required by 21 CFR 807.92(a):

## 1. Device Identification

**Submitter:** GBS Commonwealth Co., Ltd.
#C-309, 168 Gasan Digital 1-ro, Geumcheon-Gu Seoul, South Korea
Phone. 82-2-6925-4469
e-mail: Jimmy.kim@gbscommonwealth.com

**Contact Person:** Jimmy Kim
**Date prepared** March, 30, 2023

| | |
|---|---|
| Trade Name | Peridot-TD Spacer system (The Peridot-TD Intervertebral body fusion system) and Anterior cervical interbody fusion - ACIF (The Peridot-TD Anterior Cervical Intervertebral body fusion system) |
| Regulatory Class | Class II |
| Classification Name | Intervertebral body fusion device (21 CFR 888.3080) |
| Panel | Orthopedic |
| Product Code | ODP, MAX |

## 2. Purpose of 510(k)

The GBS Commonwealth Co. Ltd., here by submits this submission: for Initial product Introduction of Peridot-TD Spacer system and Anterior Cervical Interbody fusion system

## 3. Predicate or legally marketed devices which are substantially equivalent

- Primary Predicate Device : K210497 SeaSpine Spacer System NM, SeaSpine Cambria System
- Additional Predicate Device : 1) K213980 Peridot Spinal Interbody System, GBS Commonwealth

2) K213755 Peridot-PT Intervertebral fusion system, GBS Commonwealth

3) K200551 MectaLIF Transforaminal TiPEEK, Medacta International SA

## 4. Description of the Device

The Peridot-TD Cages are intervertebral fusion device manufactured from poly-ether-ether-ketone (PEEK) per ASTM F2026 with tantalum markers per ASTM F560 for radiographic visualization. The Peridot-TD Cages have a 0.5 ~ 1.0micron thick surface coat of commercially pure (CP) titanium per ASTM F67.

And some cages holders are made of titanium alloy as per ASTM F136.

The Peridot-TD Cages intended to stabilize the spinal segment, restore intervertebral height and to facilitate interbody fusion in the cervical (C2-T1) and lumbar spine (L2-S1).

Designed to treat cervical and lumbar degenerative disc disease, the platform consists of the Cervical, Transforaminal (TLIF), Lateral (LLIF), Anterior (ALIF) and Transforaminal / Posterior Lumbar (T/PLIF) Systems.

Each system features a full breadth of sizes, footprints, heights and angles.

The devices are intended to be used with supplemental spinal fixation, either applied anterior or posterior (e.g. using posterior pedicle screw and rod system, anterior plate and screw system, or lateral plate and screw system). The implant cages are supplied sterilized.

The hyperlordotic lumbar cages (>20 degree) should be an anterior plate system as the form of supplement fixation.

The device is supplied with its specific instruments. The device must be used in combination with the dedicated instruments supplied. The specific instruments are supplied dedicated tray and non-sterile.

## 5. Indication for Use

Anterior cervical interbody fusion - ACIF (The Peridot-TD Anterior Cervical Intervertebral body fusion system)

The Peridot-TD Anterior Cervical Intervertebral body fusion system is intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical

disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at one or multiple contiguous levels from C2-T1. The Peridot-TD Anterior Cervical Intervertebral body fusion system is also to be used with supplemental fixation systems that have been cleared for use in the cervical spine.

These patients should have had at least six weeks of nonoperative treatment.

The Peridot-TD Anterior Cervical Intervertebral body fusion system is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

Peridot-TD Spacer system (The Peridot-TD Intervertebral body fusion system)

The Peridot-TD Intervertebral body fusion system is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft.

The Peridot-TD Intervertebral body fusion system is to be used with supplemental fixation. Patients should have at least six (6) months of nonoperative treatment prior to treatment with an intervertebral cage.

6. **Comparison of the technological characteristics of the subject and predicate devices**

The Peridot-TD Anterior Cervical Interbody fusion and Peridot-TD Spacer System are considered substantially equivalent to the primary predicate SeaSpine Spacer System NM,SeaSpine Cambria System K210497 and additional predicate devices K213980 ,K213755 and K200551.

They are similar in design, material, scientific technologies and indications for use.

7. **Performance Testing**

The worst-case devices were tested.

1) Anterior cervical interbody fusion - ACIF (The Peridot-TD Anterior Cervical Intervertebral body fusion system)

- Static Compression (ASTM F2077)
- Static Torsion (ASTM F2077)
- Fatigue Compression (ASTM F2077)
- Fatigue Torsion (ASTM F2077)
- Subsidence (ASTM F2267)
- Static Tensile (ASTM F1147)
- Static Shear (ASTM F1044)
- Fatigue Shear (ASTM F1160)
- Wear (ASTM F1978)

2) Peridot-TD Spacer system (The Peridot-TD Intervertebral body fusion system)

- Static Compression (ASTM F2077)
- Static Compression-shear (ASTM F2077)
- Fatigue Compression (ASTM F2077)
- Fatigue Compression-shear (ASTM F2077)
- Subsidence (ASTM F2267)
- Static Tensile (ASTM F1147)
- Static Shear (ASTM F1044)
- Fatigue Shear (ASTM F1160)
- Wear (ASTM F1978)

8. **Conclusion**

Based on the information provided in this premarket notification of GBS Commonwealth Co., Ltd. concludes that Anterior cervical interbody fusion – ACIF and Peridot-TD Spacer are substantially equivalent to predicate devices.